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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/779,993

02/17/2004

James D. Lewis JR.

HT-5755 DIV

1329

29200

7590

07/24/2007

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EXAMINER

MOHANDESI, JILA M

ART UNIT

PAPER NUMBER

3728

MAIL DATE

DELIVERY MODE

07/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/779,993

Applicant(s)

LEWIS ET AL.

Examiner

/Jila M. Mohandesi/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 22, 25, 26 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 22, 25, 26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 34-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims are directed to a way of filling the flexible bag and not the flexible bag itself.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7, 11-12, 22, 25 and 28-33 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361). Johnson '361 discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, permanent seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container and a fitment (see column 6, lines 57-61). See Figures 1 and 2 embodiments and column 1, lines 11-21.

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Johnson '361 discloses that the flexible containers are utilized in medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma. Regarding the actual product or composition (concentration of at least 20% albumin), the actual composition is merely a matter of user preference and entirely obvious to use whatever composition as desired. The flexible polymeric bag of Johnston '361 is capable of holding concentration of at least 20% albumin. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to store albumin concentrations in the flexible polymeric bag of Johnston '361, since the bag of Johnston '361 is suitable and utilized in the medical industry for containing, inter alias, parenteral solutions, dialysis solutions, frozen drugs and plasma (which contains albumin).

It is noted that, in the seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this seal is formed prior to filling of the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tube area, see column 6, lines 57-61 and Figure 2 embodiment.

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49.

With respect to claim 29, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

The limitation under Official Notice is now taken as admitted prior art, therefore, with respect to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the admitted prior art to mix albumin with sterilized water and stabilizers.

With respect to claims 28 and 32 and the strength of the seal, this would be a design choice depending on the strength desired and cost of manufacturing.

4. Claims 8 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Johnston '361 as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as described above discloses all the limitations of the claims except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

5. Claims 9-10 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston '361 as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitation of the claims except for it is silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively log tabs are formed to facilitate

opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

Response to Arguments

6. Applicant's arguments filed 05/07/2007 have been fully considered but they are not persuasive.

The seal area where the fitment/fill tube is heat sealed to the outside layer of the flexible bag the seal area will be free of albumin concentration (since this seal is formed prior to filling of the flexible bag with albumin) and a permanent heat seal is formed around the fitment/fill tube area, see column 6, lines 57-61 and Figure 2 embodiment.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Jila M. Mohandesi/ whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jila M Mohandesi/
Primary Examiner
Art Unit 3728

JMM
July 16, 2007